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EAA Convention Proceedings

EU HTA – Procedural Insights & First Learnings

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* The EAA Fall Convention 2025 takes place on November 6/7th at the Université Paris Cité, Villemin Site, in Paris, France.
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AGENDA

Thursday, November 6th, 2025:

Public Session

15:30 Introduction & Setting the Scene (J-F. Bergmann, Université Paris Cité/ F. Houÿez, EURORDIS)
15:50 Welcome Message (MEP V. Andriukaitis)
16:00 Plenary Session Part 1 – Focus on Procedural Insights
- Status Review from the DG Santé Perspective (Leslie Pibouleau, DG Santé)
- Status Review from the MS Perspective (France; Pierre Cochat, HAS)
- BCCH – Support for the HTAR Implementation (Marcus Guardian, BCCH)
- Insights from EMA's Perspective (Michael Berntgen, EMA)
- Process Feedback Patients (François Houÿez, EURORDIS)
- Process Feedback Clinicians (Bernhard Wörmann, DGHO)
- Process Feedback HTD (James Ryan, EFPIA)

followed by Plenary Discussion

17:30 Coffee Break
17:45 Plenary Session Part 2 – Roundtable on EU HTA KPIs
- Recap of KPIs from Spring Convention Berlin (Elaine Julian, EAA)
- Patient Perspective (Antonella Cardone, CPE)
- Hematology Perspective (Étienne Lengliné, EHA)
- System Level/ Member State Perspective (Germany; Frank-Ulrich Fricke; TH Nürnberg)
- Health Technology Developers' Perspective (Maria João Garcia, Roche)

18:45 Sustain HTA – Sharing Status and Insights (Wim Goettsch, Utrecht University)
19:00 End of Public Session

Friday, November 7th, 2025:

EAA Working Session

08:30 Welcome (M. Pavlovic-Ganascia, Sabouraud Health Center/ M. Toumi, Aix Marseille University)
08:35 Involvement of Experts and HTA Bodies
- Oncology Perspective (Jean-Yves Blay, Centre Léon Bérard Lyon)
- Update from the Coordination Subgroup JCA (Camille Thomassin, HAS & EU HTACG Subgroup JCA)
- Poland's footprint on the EU level regarding HTA (Anna Kowalczuk, AOTMiT)
- National Trade Association Insights (France; Laurent Petit, LEEM)

09:15 Introduction to Break-Outs & KPI Measurement Matrix (Elaine Julian/ Thomas Desmet, KU Leuven)
09:30 Break-Out Sessions: Measuring KPIs
1) Patient Perspective (A. Cardone/ M. Danner/ F. Gianfrate)
2) Clinician Perspective (É. Lengliné/ S. Rosenfeld/ B. Wörmann)
3) HTD Perspective (S. Jouan/ C. Sapede/ J. Ryan)
4) Member State/ HTA-body Perspective (M. Rutten-v. Mölken/ R. Doeswijk/ M. Flume)

Coffee Break during Break-Out: available from 10:30

11:15 Report from Break-Out Groups (Facilitators)
12:00 Final Panel Discussion (M. Pavlovic-Ganascia/ M. Toumi)
12:25 Outlook Spring Convention Brussels (J. Ruof, EAA)
12:30 End of Convention

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EU HTA – Procedural Insights & First Learnings

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The EU HTA Regulation (EUHTAR)[1] covers two key elements – Joint Scientific Consultation (JSC) and Joint Clinical Assessment (JCA) – in two areas of application – medicinal products, and medical devices and in vitro diagnostics (IVD) (table 1). The Regulation came into force at the end of 2021, and first JCA procedures for medicinal products in oncology and advanced therapy medicinal products (ATMPs) have commenced since January 12th, 2025, with the list of ongoing medicinal product JCAs being available online[2]. JCAs for medical devices and IVD will begin in 2026. During the first JSC request period three medicinal products were selected for JSC, while JSC for medical devices and IVD is currently still in the third pilot phase[3].

Reviewing the status of the implementation based on table 1 one might suggest that only one out of the four fields (i.e., JCA on medicinal products) is in operating mode, while the other three fields should currently be color-coded in yellow, if not red, due to the following shortcomings and challenges.

- *The publicly available list of ongoing JCAs harbours a number of interesting insights:*
  - *Publication of ongoing procedures after EMA has validated the respective regulatory dossiers occurs rather late considering the already very tight timelines of the process and only includes the condition for which the medicine is proposed, without any detailed information on the proposed target indication.*
  - *The publication of the Frequently Asked Questions document by DG Santé, clarifying which medicinal products are subject to JCA, indicates that different from oncology medicines, ATMPs and ODs (from 2028 on) are also subject to EU HTA when they are already available on the market. This interpretation of the regulation's wording by DG Santé caught some of the involved stakeholders by surprise.*
  - *Finally, initial assignment of (co-) assessing HTA bodies may indicate developing clusters: The German HTA body Institute for Quality and Efficiency in Health Care (IQWiG) participates in four out of nine assessments and is the main assessor for the two lung cancer medicines; the French HTA body Haute Autorité de Santé (HAS) is (co-) assessor in the two ATMP procedures; among the smaller members states only Ireland (co-) chairs two assessments. Spain and Italy have not yet been appointed as (co-) assessors for any of the JCAs and Austria, Belgium, Denmark, Hungary, Norway, Poland, Portugal, Slovenia and Sweden signed up for one (co-) assessment each.*
- *While JCAs for medicinal products started in January 2025, both, JSC and JCA procedures for medical devices and IVDs are lagging behind. Product characteristics, evidence standards, as well as regulatory and market access pathways are fundamentally different from those for medicinal products. Therefore, a high level of procedural uncertainty remains with regards to the introduction of EU HTA for medical devices and IVDs, not least with the interface of the EUHTAR and the 2017 EU Medical Device Regulation[5].*
- *Currently, the German HTA Body G-BA is conducting ~250 early advice procedures per year indicating the vast need for such advice[6]. Even though EU HTA JSC capacities are expected to increase over time, a total of only about 10 JSCs are expected to be performed in 2025. The striking difference between the national advice capacities in Germany and the EU capacities clearly indicate a major shortcoming for the latter. Furthermore, implementing JCA procedures without preceding JSC opportunities for HTDs is counterintuitive. In particular, in the early implementation phase of the EUHTAR thorough advice mandatory to guide Health Technology Developers with JCA preparations. Developing high quality dossiers based on clinical data addressing JCA evidence requirements without prior advice poses a major challenge for HTDs.*

Procedure	Medicinal Products	Medical Devices and IVDs
JSC	3 products selected in the first request period	Third Pilot Phase
JCA	Started on Jan 12th, 2025; as of September 2025, JCAs for 9 medicinal products have started	Not yet started

Table 1: Crosstable illustrating the status of the implementation of the EUHTAR.

At the EAA Spring Convention 2025 in Berlin a framework for performance measurement for EU HTA was developed. Stakeholder-centric Key Performance Indicators (KPIs) were identified in a modified Delphi Procedure covering patient, clinician, HTD, and System/Member State perspectives[7]. During the EAA Fall Convention 2025 at Université Paris Cité, this work will be expanded upon and proposals for measurement and tracking of the identified KPIs will be developed. In addition, first procedural experience with the ongoing JSCs and JCAs will be shared and discussed.

Anecdotal feedback that has so far been shared, mainly by patient, clinician, and HTD experts, indicates considerable procedural challenges regarding the KPI on 'successful and meaningful stakeholder involvement':

- *Provision of more detailed Information would support the identification of suitable respective patient and clinician experts by the associations.*
- *Sharing of information on which experts were finally selected with the recommending associations and clarification regarding to what extent selected experts may share information regarding their involvement in those procedures with their peers would strengthen the process.*
- *Optional inclusion of personal interaction opportunities for questions or clarification in addition to electronic communication channels would allow experts to contribute their insights and experience more efficiently.*
- *Clarification of scope of requested input i.e., whether advice was aimed for JSCs and/or JCAs and regarding the specific product in scope would facilitate high quality of contributions.*
- *Optimized management of timelines is critical to ensure meaningful involvement and feedback.*
- *Also, stakeholders mentioned highly conservative interpretation of Conflict-of-Interest regulations may lead to exclusion of best available expertise.*

At all previous EAA conventions meaningful stakeholder involvement was identified as one of the most critical success factors for the implementation of the EUHTAR. While more systematic tracking of the performance of the EU HTA procedure is currently being prepared, early indicators suggest major shortcomings in the successful and meaningful involvement of patients and clinicians in the initial procedures. Considering the relevance of the patient and clinician perspective to balance and 'humanize' those highly technical procedures a key focus of the upcoming EAA convention in Paris will be how to ensure a balanced inclusion of all three pillars of evidence-based medicine in the EU HTA process, i.e.: i) clinical data, ii) patient insights, and iii) needs/ clinician experience and perspective.

The organizing committee would like to thank Université Paris Cité for hosting the EAA Fall Convention 2025 within their premises.

We are very much looking forward to a successful EAA Fall Convention 2025 in Paris.

Mira Pavlovic-Ganascia, Jean-François Bergmann, François Houÿez, Patrick Tilleul, Mondher Toumi & Jörg Ruof
on behalf of the EAA Faculty

1) https://eur-lex.europa.eu/eli/reg/2021/2282/oj; 2) https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en; 3) https://health.ec.europa.eu/document/download/939f2e10-a136-486d-9cdf-faae6aff5ed6_en?filename=hta_20250611_min_en.pdf; 4) https://health.ec.europa.eu/document/download/b81a42c4-b2ba-47bc-b807-0c667c8de32e_en?filename=hta_htar_qa-jca_en.pdf; 5) https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng; 6) https://www.g-ba.de/downloads/17-98-5911/250611_G-BA_Geschaeftsbericht_2024_BF.pdf?; 7) Julian E, Xander N, Boumaki K et al. Development of a Performance Measurement Framework for EU HTA. 2025; Submitted; JMAHP

EAA Convention Speaker Abstracts

Status Review National Perspective (France)

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The HTAR relies on the introduction of two European assessment procedures: the joint scientific consultation (JSC) during the research and development phase, and the joint clinical assessment (JCA) during the marketing authorization (MA) phase. These two steps precede the national appraisal which may also include the early access process in France.

The French National Authority for Health *(Haute Autorité de santé, HAS)* -like other European HTA agencies- now combines an HTAR-based activity for certain drugs (new molecules in haematology/ oncology and advanced therapy medicinal products, ATMP) in addition to its previous assessment/ appraisal activity for all other medicinal products.

Indeed, the appraisal of a health technology (HT) leading to reimbursement and pricing remains the competence of each individual Member State: HT developers (HTDs) must still submit a reimbursement request, HAS members will have access to the clinical data provided at the European level, the Transparency committee (TC) will continue to evaluate HTs according to its doctrine, and the Ministry will continue to make reimbursement decisions.

HAS has introduced preliminary measures: i) creation of an adequate committee within HAS (weekly meeting); ii) information/ training of HAS members; iii) information/ training of TC experts; iv) information/ training of representative of HTD; v) online information www.has-sante.fr; vi) publication of a special issue of *Quart Med Rev* (French journal in English).

Then HAS had to set global actions for both staff and experts: i) involvement of the whole Medicinal Product Assessment Office (SEM), with 2 delegates for JSC and 2 delegates for JCA, in addition to coordination, regulation and information; ii) expert input (clinicians and patients, members of the TC or external experts if needed) and validation of the national PICO by the TC board.

Which procedures are unchanged at the national level? i) early access requests submitted before obtaining MA must include all available data); ii) the TC as well as the Economic Committee for Health Products (CEESP) will continue to issue their opinions according to their evaluation principles); iii) standard procedure for health technologies not covered by JCAs will be assessed by the HAS in accordance with the current procedure.

Which procedures are affected at the national level? i) national early dialogues: medicinal products that have undergone or will undergo a JSC will not be eligible for an early national meeting; ii) early access post-MA; iii) standard evaluation procedures (the clinical data provided at the European level will not be requested again at the national level).

The current ongoing JCAs are: 8 drugs for cancer and 1 for ATMP; assessors/co-assessors are Austria 1, Belgium 1, Denmark 1, France 2, Germany 4, Hungary 1, Ireland 2, The Netherlands 1, Norway 1, Poland 1, Portugal 1, Slovenia 1, Sweden 1.

As a *conclusion*, following this first experience, some issues can be drawn. There are some commune challenges: i) implementation of new processes that necessitate refinement and optimisation; ii) coordination and harmonisation between the first JCAs. Some challenges are specific to the assessor: i) complex JCA: PICO requiring numerous sub-populations; ii) complex PICO consolidation across 27 Member States. And other challenges are related to the reviewer of other JCAs: i) national procedures enabling to adequately address the national PICO (involvement of clinician and patient experts, validation by the TC board; ii) implement this process and make it sustainable throughout time.

The Brussels Centre for Collaboration in Health (BCCH) – Support for the HTAR Implementation

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In 2023 European collaboration on health technology assessments (HTA) was elevated from sequential project-based approaches[1] towards a permanent legal framework, the HTA Regulation (HTAR). The HTAR establishes a predictable legal framework for Health Technology Developers (HTD) by defining two main procedures, Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs). European HTA bodies (HTAb) are brought together under the HTA Coordination Group (HTACG), which through its "sub-groups" implement the assessment work. This work is financially supported by the European Commission[2].

The European Commission introduced the financial support for HTACG members via a tender based Framework Contract. The tender was published in October 2024. The majority of HTACG members came together and formed a consortium that replied to the tender procedure. This "HTA Framework Contract Consortium" (HTA FCC)[3] was formed under the leadership of the Belgian National Institute for Health and Disability Insurance (NIHDI)[4] and signed the Framework Contract[5] in January 2025. The consortium brings together more than 35 European HTA organisations that actively participate in the production of JCAs and JSCs.

For the day-to-day management of the Framework Contract NIHDI established a new legal entity which serves as administrative body to the Lead Partner and as service provider to the consortium. The Brussels Centre of Collaboration in Health (BCCH) in its role as administrative body is a not-for-profit[6] organisation under Belgian law.

BCCH[7] provides services to the consortium that benefit from a centralised approach. These services focus on supporting the consortium as a whole and individual consortium partners in their activities under the framework contract. BCCH provides a secure project management infrastructure, sets up meetings for ongoing JCA and JSC procedures, supports the work of the individual assessor and co-assessor (ACA) teams, provides medical editing for JCA and JSC final reports, manages the contractual and financial workflows of the consortium, supports the coordination of consortium member activities and facilitates their joint work.

For both, JCA and JSC, patients and experts are required to provide insights into each individual product assessment. BCCH is charged with contracting selected patients and experts[8]. For this work the "HTA patient and expert hub" was initiated. BCCH collaborates on the hub with European patient organisations in providing relevant information material that helps patients to prepare for their JCA/JSC involvement. The hub provides secure spaces for each individual patient and expert. The secure environment supports the exchange of contract and payment specific information.

The "HTA Patient and Expert Hub" is coordinated in alignment with the HTA Secretariat, the HTA Stakeholder Network, relevant European umbrella organisations and other European initiatives supporting patient and expert contributions to HTAR processes. This joint effort establishes a support mechanism for patients and experts in their participations in European HTA procedures.

The HTA FCC lead-partner, NIHDI, will continue to provide support to consortium members via BCCH in a pragmatic and timely manner. Especially in the early phase of the HTAR implementation BCCH provides a framework that can address unforeseen obstacles and support developing solutions by consortium members.

BCCH Board of Directors is chaired by Dr. Francis Arickx (NIHDI) and includes members from Ireland[9] and Portugal[10].

1) Between 2009 and 2023 several EU funded projects of EUnetHTA (European Network for HTA) were implemented leading up to planning and implementing of the HTA Regulation. 2) HTAR, Art. 27 "Union Financing". 3) It is important to distinguish the two from each other, even though HTACG and HTA FCC membership overlaps to a large percentage, these are fundamentally different bodies. The HTACG is regulated via the HTAR. The HTA FCC provides the mechanism for the HTACG implementing the HTAR with the help of EU financial support via a framework contract. 4) NIHDI is also referred to with the acronym RIZIV-INAMI representing the Dutch and French abbreviations. 5) The framework contract runs for up to 48 months and covers a total of 34 million EUR. 6) It carries the status of "association sans but lucrative (asbl)" / "vereining zonder winstoogmerk (vzw)". 7) It is important to note that the work of the HTACG is supported by the HTA Secretariat (HTAR Art.27) situated in DG SANTE. The role of the HTA Secretariat is defined in the HTAR. BCCH is not linked to the HTA Secretariat institutionally or otherwise. Both the HTA Secretariat and BCCH collaborate closely in the implementation of the framework contract. 8) The European Commission, via its HTA Secretariat, is responsible for identifying relevant patients and experts. The HTA Secretariat, after having checked the individual conflict of interest status, presents a list of candidates to the relevant (JCA/JSC) sub-group which then selects. 9) National Centre for Pharmacoeconomics (NCPE). 10) Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED).

Insights from the EMA Perspective

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The new European HTA Regulation, applicable since January 2025, recognises the value of collaboration at the regulatory/HTA interface. The aim is to build synergies between regulatory evaluation and HTA along the medicine lifecycle.

Building on detailed and forward-looking implementation work, first experiences with the operations at the regulatory/HTA interface are now made. This particularly concerns the provision of information from the assessment of Marketing Authorisation Applications (MAAs) that are subject to Joint Clinical Assessment (JCA). The latter is conducted in parallel to the regulatory review resulting in a procedural connection that requires operational management. Several products are currently undergoing such European-level parallel reviews[1]. To facilitate the timely JCA preparation, well-defined elements from the ongoing regulatory review are to be provided by EMA to the HTA secretariat, ensuring that the respective remits are respected. With the progress of the various applications, this by now already includes the provision of information from the adopted list of questions.

Furthermore, the first four requests for parallel Joint Scientific Consultations (JSC) under the new Regulations are identified. Whilst this work builds on several years of project-level experience, the new legal framework provides specific requirements. Other exchanges of information at the interface include the provision of forecast data to inform the planning for future HTA work, as well as the identification of potential experts (patients, carers and clinicians) to support such nominations for JCA and JSC, respectively.

The experiences are also relevant for better prospective evidence planning by developers. Here the Joint HTAb/regulatory position paper on robustness of evidence and uncertainty management (see Position paper) provides valuable insights for the design of clinical development programmes and serves as framework for future topics of mutual interest[2].

1) https://health.ec.europa.eu/document/download/d947533e-7e4e-4e82-a9c6-e06830d708f8_en?filename=hta_ongoing-jca_en.xlsx;
2) https://www.ema.europa.eu/en/documents/other/joint-htab-regulatory-perspectives-understanding-evidence-challenges-managing-uncertainties-exploring-potential-solutions_en.pdf

Process Feedback: Clinicians

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Comparison is the conceptual backbone of the EU HTA procedure for new drugs. Their value is assessed in comparison to the current standard. The relevant clinical elements are well summarized in the PICO scheme. The first experiences on the clinical side were dominated by two questions:

- What is the current treatment standard?
- Who knows it?

What is the current treatment standard?

In principle, treatment standards are defined by guidelines. Guidelines are evidence-based recommendations for action. They bridge the gap between the rapidly growing body of external evidence in many areas and the individual situation of patients. Unlike regulations or directives, guidelines serve as decision-making aids. Many activities in the past two decades have focused on the implementation of guidelines into the healthcare system and the individual physician-patient interaction.

However, in modern oncology the implementation of guidelines is increasingly determined by national / regional access to the recommended diagnostic and therapeutic tools. A recent analysis in hematooncology has revealed an enormous heterogeneity with the EU member states. The gaps are even widening. Differences relate to almost all aspects of the PICO elements: population of treated patients, comparator availability and outcome parameters.

Who knows it?

Many EU HTA discussions in the past months have dealt with the identification of clinical experts. Based on legal aspects, selection has centred on the criteria of conflict of interests. Although important, this HTA discussion is not congruent with the discussion within national and international medical societies in the creation of guidelines. The selection criteria focus on the quality of experts for the respective indication covering all areas of healthcare ranging from epidemiologists to oncological practitioners. The selection procedure aims at exclusion of as few key opinion leaders as possible. Medical societies increasingly foster the concept of collective intelligence and try to balance ever-existing conflicts of interests by detailed discussion and consensual decisions.

The current experiences in the EU HTA process challenge the selection process of medical experts. Insufficient medical expertise may affect the quality of the JCA and jeopardize the final evaluation.

From Policy to Practice: The Health Technology Developer's Role, Experience and Expectations

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The Joint Clinical Assessment (JCA) is unprecedented in ambition and scope in the field of health technology assessment (HTA), providing a significant opportunity to improve patient access to new medicines in the European Union (EU) and avoid duplication of work for both health technology developers (HTDs) and HTA bodies across the EU. Up until October, only 9 JCAs have started, and the first completions are not expected until 2026. However, based on the experience to date, it is important that we celebrate where the process is working and become solution-focused where there may be barriers.

All stakeholders who have been part of an individual JCA procedure will have their own experience. From a HTD perspective, there will be rapid learnings within each individual company, but their experience of the JCA process itself may also not be reflective of others. This may be because of different levels of internal readiness, uniqueness of their evidence package, interpretation of the Regulation and procedural guidance documents; but it may also be due to differences in their interactions and information exchange with the HTA Secretariat and JCA assessors. For the latter two we are already seeing adaptation and efforts to both increase clarity on and improve the process.

But there remains much more to do, and we cannot sit still. We have now transitioned from "Policy into Practice", and it is only at this point that untested procedures are truly being challenged, and that unknown complexities have become known. From an HTD perspective, three criteria are essential for successful implementation:

1.Improved health outcomes: the fundamental measure of the Regulation's success is its ability to drive better health outcomes for patients across Europe.

2.Streamlined national HTA and improved patient access: the Regulation must not become another barrier for innovative medicines in Europe, particularly for SMEs; the additional investment and analyses required upfront by HTDs, compared to pre JCA, must be offset with usage of the report, more efficient national procedures and a shorter duration of the national decision-making process to improve availability and time to patient access.

3.Process efficiency and workability: HTDs need predictability and clarity throughout the JCA process, from the starting date and final scope delivery, through to submission deadline. HTD engagement before and during the process can make a difference too, ensuring high quality submission readiness. Crucially, HTDs also need to reliably predict requested PICOs to minimize substantial additional work beforehand. This requires clearer guidance on the scoping process and consolidation, and an optimization and convergence of PICOs over time.

To these ends, EFPIA and other HTD organisations in the EU HTA Stakeholder network are planning to track the process and experience of their members to provide regular feedback and solutions to ensure the Regulation delivers the performance envisioned, as well as inform the efficiency and added value of the Regulation for the Commission's 2028 evaluation.

Sustain HTA – Sharing Status & Insights

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SUSTAIN-HTA aims to support national and European advancement of HTA by mapping existing tools, identifying new methodological developments that match HTA needs, and making them easily findable and accessible for European HTA bodies. It is a Horizon Europe Coordination Support Action that started in 2024 and will continue until 2028. It consists of 15 organisations, of which seven are national and regional HTA bodies.

SUSTAIN-HTA supports national HTA bodies in mobilising new HTA methods among their workforce, building excellence in knowledge and skills, and supporting the development of HTA internationally. Aligned with the methodological developments as part of the new EU HTA regulation, the project will establish a mechanism for a fair and balanced exchange between HTA bodies and academia to regularly assess the needs of HTA bodies, in parallel with a methods observatory that maintains up-to-date knowledge of new HTA methods. Currently, beta versions of the Horizon Scanning Tool and the Methods Observatory are being tested and will be available in a first version by the end of 2025. Additionally, a training programme for prioritised methods will be piloted within HTA bodies. After endorsement, the implementation of these methods will be supported by a harmonised training and education framework that will be established to upskill HTA expertise. Within the project, an HTA competency framework has already been developed to characterise the different levels of HTA expertise. Additionally, a learning information management system (LIMS) has been initiated, which will serve as the framework for the new courses that SUSTAIN-HTA will develop, as well as for existing courses from other organisations and projects.

Simultaneously, SUSTAIN-HTA will launch a fellowship programme at the beginning of 2026, providing opportunities for mid-level HTA employees from less experienced HTA bodies to become familiar with more advanced HTA methods. SUSTAIN-HTA has established a long-term dissemination and communication structure among all stakeholders to ensure a feedback loop between the methodological needs of HTA bodies and their associated training needs. The project has initiated the HTA Network, which includes representatives from more than 15 HTA bodies across Europe, as well as the Stakeholder Forum, comprising representatives from all relevant stakeholders. Moreover, the SUSTAIN-HTA Expert Forum has been established, which includes representatives from EU HTA-focused research groups, as well as from societies such as HTAi, ISPOR, and Cochrane.

Finally, SUSTAIN-HTA is currently developing a business model that will ensure the continued effectiveness of its products beyond the project's conclusion in 2028. It is anticipated that in this effort, the project will seek collaboration with external partners to ensure that the products become a more significant part of the EU HTA ecosystem, maintaining a close link to the EU HTA Coordination Group and its subgroups.

Involvement of Experts & HTA Bodies – Oncology Perspective

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The increasing complexity of cancer care, driven by rapid advances in precision medicine and novel therapeutics, demands early and meaningful collaboration between clinical experts and Health Technology Assessment (HTA) bodies. In oncology, this interaction is crucial to ensure that innovative therapies reach patients in a timely, equitable, and evidence-based manner. However, the current landscape remains fragmented, with variability across countries in how expert opinions are integrated into HTA processes, and in how declaration of interest impact the capacity of experts to provide an expert opinion on these complex topics. Oncologists play a pivotal role in contextualizing clinical evidence, interpreting surrogate endpoints, and assessing unmet medical needs, particularly in rare and molecularly defined subgroups.

The ESMO Magnitude of Clinical Benefit Scale (MCBS) has emerged as a valuable tool to objectively grade the clinical value of anticancer therapies, providing a transparent, standardized framework that complements HTA evaluations. By quantifying meaningful patient benefit in terms of survival, quality of life, and toxicity, the MCBS supports prioritization of high-value interventions and facilitates alignment between clinical relevance and economic assessment. Integration of MCBS into HTA discussions could harmonize decision-making processes, enhance cross-country comparability, and ensure that reimbursement and access decisions reflect true clinical benefit.

From an oncology perspective, strengthening structured, transparent, and iterative engagement between experts and HTA bodies – while incorporating instruments such as the ESMO-MCBS – is essential to bridge the gap between innovation and patient benefit, fostering a more efficient and patient-centered value assessment ecosystem in cancer care.

Update from the HTA Coordination Group Subgroup JCA

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The Regulation (EU) 2021/2282 on health technology assessment (HTAR) entered into force on 11 January 2022 and applies from 12 January 2025.

This new and permanent EU-framework introduces a single EU-level submission file for joint clinical assessments (JCAs) in order to ensure pooling of resources at the EU level and strengthening the scientific quality of HTA across the EU while avoiding duplication of assessments at national level. It also establishes faster procedures requiring JCAs to be completed within 30 days after the authorisation of the medicine. At last, it implies the systematic consultation of patients and clinicians during the preparation of the assessments as well as the involvement and consultation of the HTA stakeholders.

As a first step, Joint Clinical Assessments (JCAs) cover marketing authorisation applications for a new cancer medicine or an advanced therapy medicinal product (ATMP). The scope will be extended to orphan medicines in January 2028 and will as of 2030 cover all new medicinal products. Selected high-risk medical devices will also be assessed as of 2026 (see also the factsheet Implementing the EU Health Technology Assessment Regulation)[1]. In that respect the implementing act on the JCAs for MDs received a positive opinion from the HTA Committee on 19 September 2025.

The product specific joint work under the HTA regulation has started in January 2025, and **as of September 30, nine JCAs have been initiated for medicinal products. The list of ongoing JCAs is publicly available on the European Commission website[2].** The Joint Scientific Consultations (JSCs) have also started, with the first and second request periods launched respectively in February and June 2025.

The HTA authorities are fully invested in the joint work, whether as assessor or co-assessor for the ongoing JCAs, or as Member States representatives in the JCA, JSC, Methodological and Procedural Guidance and/or Emerging Health Technologies subgroups of the HTA Coordination Group.

Co-creation of effective patient and clinical expert involvement is key and thus a working group on the identification of patients and clinical experts was launched within the **Health Technology Assessment Stakeholder Network (HTA SN),** as reported **during the fifth meeting of the SN held on 1 July 2025 in Brussels[3]. It was also acknowledged during this meeting to improve interactions with Health Technology Developers in the pre-submission stage.**

1) https://www.ema.europa.eu/en/documents/other/joint-htab-regulatory-perspectives-understanding-evidence-challenges-managing-uncertainties-exploring-potential-solutions_en.pdf;
2) https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fhealth.ec.europa.eu%2Fdocument%2Fdownload%2Fd947533e-7e4e-4e82-a9c6-e06830d708f8_en%3Ffilename%3Dhta_ongoing-jca_en.xlsx&wdOrigin=BROWSELINK;
3) https://health.ec.europa.eu/document/download/0007ee07-3019-4d3c-9de2-83beeca430a4_en?filename=hta_20250701_mi_en.pdf

Poland‘s footprint on the EU level regarding HTA

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This presentation outlines AOTMiT's *(pl. Agencja Oceny Technology Medycznych i Taryfikacji, ang. Agency for Health Technology Assessment and Tariff System)* role and activities during the final stages of the preparations for the implementation of the Regulation (EU) 2021/2282, as well as its initial experiences following the Regulation's entry into force in January 2025.

AOTMiT is a designated member of the Coordination group. Although initially cautious of EU HTA processes, AOTMiT significantly intensified its involvement in the Coordination group starting June 2024. Despite joining the preparation relatively late, AOTMiT quickly caught up with other Members by establishing internal task force dedicated to supporting the implementation process. While aligning with the EU HTA processes, AOTMiT encountered both internal and external challenges, including resource limitations, need for the adaptation of the Polish law to the Regulation, and the necessity of strengthening stakeholder engagement while ensuring compliance with provisions for the protection of confidential information. Recognizing the pivotal role of the stakeholders, AOTMiT is committed to involving clinical experts in the scoping process to gather insights into real-world clinical practice and identify unmet clinical needs within the Poland's healthcare system.

The Agency faced with the increasing number of tasks related to the EU HTA, AOTMiT is planning to expand its workforce and invest in comprehensive training. These efforts aim to enable AOTMiT to take on more roles in Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC). To support capacity building opportunities and ensure full involvement in the processes AOTMiT joined the consortium for the single framework contract governing JCA and JSC in November 2024.

As of September 2025, AOTMiT continues to serve as a co-assessor in the JCA for the Autologous melanoma-derived tumor infiltrating lymphocytes and submitted 9 national PICO proposals and actively collaborates within all of the subgroups of the Coordination Group.

AOTMiT views its support for the EU HTA as a strategic investment in the future of the HTA. JCA are expected to harmonize HTA practices across the Member States, fostering greater consistency and efficiency. At the national level JCA, may support locally submitted dossiers, potentially replacing clinical analyses, thereby accelerating the reimbursement process. Moreover, they can offer incentives for applicants and help reduce the cost of local procedures.

Involvement of Experts & HTAb - National Trade Association Insights

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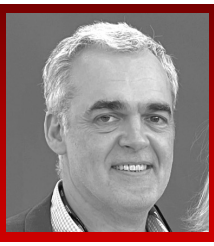

Market access in France and the role of patients before and after the implementation of HTA regulation?

How French patients can contribute to the definition of PICO and the assessment of a drug's added value?

What role do clinical experts and medical societies play in market access in France?

Challenges for small to mid-sized companies with EU HTA

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EUCOPE is pleased to partner with EAA for this year's fall convention to organise a pre-conference focused on the needs of small to mid-sized companies.

The very first Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC) have now begun, and we have come one step closer to achieving the idea for a "one-stop-shop" for health technology assessment at the European level.

When the new framework for joint work was first proposed by the European Commission it was welcomed by the pharmaceutical industry, as a unique opportunity for greater alignment on HTA requirements and reduction of duplicative assessments, thereby reducing the burden faced by companies.

For the smaller biopharmaceutical companies, more harmonised HTA requirements will be especially important, since they typically have much smaller market access teams, less resources available for evidence generation, and smaller portfolios, making it much more difficult for such companies to successfully navigate the fragmented HTA landscape in Europe.

While no JCA has been completed yet, a few issues, and certainly valuable lessons, have already been drawn from the first JCAs. To list a few, there has been a need for clarity of the timelines and communicating these early on, awareness of the procedure for early notifications from companies prior to the start of JCA, and the additional clarifications on the scope of products subject to JCA.

With the increasing number of JCAs, additional lessons will be learned, and it will be essential to maintain an ongoing dialogue to address any potential issues as soon as possible. The HTA Stakeholder Network will be an important resource going forward to support the European Commission HTA Secretariat and the HTA Coordination Group (CG), with diverse and in-depth expertise on HTA.

EUCOPE has taken an active role in preparing our member companies for the implementation and has organised a series of webinars and in-person workshops over the last year. With input from our member companies, we are also gathering practical experiences and look forward to sharing lessons learned with the HTA CG and HTA Secretariat, to help continuously improving the functioning of the procedures.

A critical need for companies is the ability to receive scientific advice prior to the JCA. While the first JSCs have begun this year, not all companies that have applied could receive an advice meeting due to limited capacity. The number of request periods and advice meetings will be scaled up from next year, however with Orphan Medicinal Products subject to JCA from 13 January 2028, the need for additional JSC slots will only increase.

There is therefore an urgent need for solutions for providing additional capacity for advice meetings. Possible options could include an earlier introduction of the fee-paying mechanism, or the continuation of the interim scientific advice that was coordinated by G-BA, to offer additional advice meetings beyond the JSC slots that will be available next year.

European Medicines Agency‘s Support for SMEs

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Small and medium-sized enterprises (SMEs) are vital drivers of innovation in the pharmaceutical sector. Recognising the unique challenges these companies face in developing and bringing medicinal products to market, the European Union introduced specific provisions through Commission Regulation (EC) No 2049/2005. This regulation establishes measures to promote innovation and support the development of new medicines by SMEs, including the creation of the SME Office within the European Medicines Agency (EMA), which is specifically designed to address the needs of smaller companies.

The SME Office serves as a central point of contact for micro, small, and medium-sized biopharmaceutical enterprises involved in the development and marketing of medicines. It offers a range of support services, including regulatory and administrative guidance and assistance, financial incentives, and platforms for early dialogue. A key function of the Office is to assess eligibility and grant SME status—an essential prerequisite for accessing tailored support measures. Once granted, SME status entitles companies to significant benefits, such as fee reductions or waivers for scientific advice and inspections, as well as deferrals for marketing authorisation application fees. These incentives are particularly beneficial for smaller companies that often operate with limited financial resources.

In addition to financial incentives, the SME Office provides comprehensive regulatory and administrative assistance throughout the entire product development lifecycle. This includes support in preparing regulatory submissions, accessing scientific advice, and navigating complex regulatory and administrative requirements—all with the aim of increasing predictability and the likelihood of regulatory success. The Office also facilitates knowledge-sharing and capacity-building by offering targeted training sessions, webinars, and educational materials, and by engaging with a broad network of partners and stakeholders that support SMEs in the pharmaceutical sector.

Through these initiatives, the EMA SME Office plays a crucial role in fostering pharmaceutical innovation by equipping SMEs with the guidance, tools, and incentives necessary to successfully bring new therapies to market.

Background for Break-Out Sessions:

excerpt from EAA Manuscript – under review at JMAHP

Development of a Performance Measurement Framework for EU HTA:

Stakeholder-centric Key Performance Indicators identified by the European Access Academy

Elaine Julian, Nicolas Xander, Konstantina Boumaki, Maria João Garcia, Evelina Jahimovica, Joséphine Mosset-Keane, Monica Otto, Mira Pavlovic, Giovanna Scroccaro, Valentina Strammiello, Renato Bernardini, Stefano Capri, Ruben Casado-Arroyo, Thomas Desmet, Walter Van Dyck, Frank-Ulrich Fricke, Fabrizio Gianfrate, Oriol Solà-Morales, Jürgen Wasem, Bernhard J. Wörmann, Jörg Ruof

Table: Alignment of prioritized stakeholder-centric KPIs for EU HTA with the WHO's health system goals[1]

Health System Goal	Patient Perspective	Clinician Perspective	HTD Perspective	MS/ HTAb Perspective
Health improvement		- PICO related KPI (Scope: i) Reduction of the number of PICOs over time for a specific disease; and ii) reflecting clinical standards in MS; - Addressing uncertainty (Scope: Clarity on strength/ convincing outcomes)	- PICO related KPI (Scope: Optimization)	- PICO related KPI (Scope: Exhaustiveness); - Learning & training the system
People centredness	- Successful and meaningful patient involvement; - Utilization of patient-centric/ -relevant outcome measures	- Successful and meaningful clinician involvement; -Transparency		
Efficiency of the health system	- Time to patient access§	- Time to patient access§	- Functioning JSC process (Scope: Addressing existing demand & developmental timelines); - Functioning JCA process (Scope: Workability/ realistic response timelines/ efficient communication); - Shorter duration of the national decision-making process	- Reduce duplication of effort (Scope: Utilization of JCA report and reduction of workload); - Time to patient access§
Equity of the health system	-Equity of patient access (Scope: availability across MS)§	-Equity of patient access (Scope: availability across MS)§		-Equity of patient access (Scope: availability across MS contingent on budgetary capacities)§

§ influenced by other factors
Abbreviations: HTAb: Health Technology Assessment body, HTD: Health Technology Developer, JCA: Joint Clinical Assessment, JSC: Joint Scientific Consultation, KPI: Key Performance Indicator, MS: Member State, PICO: Patient/ Intervention/ Comparator/ Outcomes, WG: Working Group, WHO: World Health Organization

1) Papanicolas I, Rajan D, Karanikolos M, Soucat A. Health System Performance Assessment: A Framework for Policy Analysis. Geneva, Switzerland: World Health Organization; 2022.

Outlook EAA Spring Convention 2026 in Brussels, Belgium

Preparing for the 2027/ 2028 Revision of the EU HTA Regulation

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Article 31 of the EU HTA Regulation stipulates that no later than Jan 13th, 2028, the Commission shall present a report to the European Parliament and to the Council on the application of the regulation.[1] The article also indicates that one year earlier, i.e., in January 2027, Member States shall report to the commission on their consideration of the joint work. Taking those tight timelines into account, EAA's Spring Convention 2026 and the envisioned subsequent peer-reviewed scientific publication will be timely to inform such systematic stakeholder feedback on the process.

Research conducted at prior EAA conventions indicated that comprehensive and meaningful stakeholder input is one of the most relevant success factors for the implementation of the regulation.[2] Consequently, the stakeholder perspective and experience sharing across key expert groups i.e., patients and clinicians, will be at the core of the convention. To further strengthen the critical patient voice in the discussions, 'Cancer Patients Europe' (CPE) will be co-chairing the spring convention together with EAA.

As a conceptual framework for the reflection and conversations at the convention, the Key Performance Indicators (KPIs) as developed at EAA's 2025 Spring Convention with the respective measurement approaches being developed during the break-out sessions of the current EAA Convention in Paris, will be leveraged.[3] Importantly, the perspectives of the various stakeholder groups involved in the process are addressed in these KPIs.

Since January 2025 Joint Clinical Assessments (JCA) have commenced, with the list of ongoing procedures being available on the DG Santé's EU HTA website and regularly updated.[4]

Joint Scientific Consultations (JSC) procedures for Medicinal Products (MP) have also started, however, in a very limited capacity; JSC and JCA for Medical Devices (MD) and *in vitro* Diagnostics (IVDs) are lagging. Key questions regarding the implementation status of the regulation may be summarized in a cross-table covering the two types of products (MP and MD/IVD) and the two procedures introduced by the regulation (JSC and JCA) (table 1).

First JCA reports will become available in early 2026 - ideal timing to review, discuss and reflect scoping results, applied methods, assessment outcomes, and procedural excellence throughout the first JCA procedures as well as looking into the progress of the other elements of the cross-table. The insights generated at the convention will be used to inform EAA's & CPE's recommendations to the 2027/28 amendment of the regulation.

For the second time, an EAA convention will take place in Brussels, at Vlerick Business School and the Belgian HTA/Reimbursement Institute RIZIV-INAMI. An adjunct session will address the development of a center of excellence focusing on RWD for HTA – the 'Centre for Inferential Causality' (CIC) at Vlerick Business School. Due to the proximity to the EU institutions holding the meeting in Brussels will also facilitate involvement and participation of the respective stakeholders and thereby support awareness for equitable access to innovative and beneficial treatments across the EU.

The organizing committee would like to thank RIZIV-INAMI and Vlerick Business School for kindly hosting the convention at their premises.

Procedure	Medicinal Products	Medical Devices and IVDs
JSC	• Available capacities and number of JSC slots; • Number and rationale for rejection of applications; • Interface of JSC with early regulatory advice and early HTA advice on national level (e.g., with HAS or G-BA); • Initial procedural insights incl. meaningful patient & clinical expert involvement; • Initial experience on general scope of questions (above product level).	• Similar questions as for Medicinal Products, however, covering the specific characteristics of Medical Devices & IVDs.
JCA	• Review of initial assessments and outcomes; • Content comparison with outcomes of regulatory assessments; • Patient and clinical expert considerations on initial outcomes; • Initial procedural insights incl. meaningful patient & clinical expert involvement; • Initial reactions from member states.	• Status of the implementation; • Any procedural insights (if available).

Table 1: Cross-table illustrating some of the key questions that will guide discussions at the EAA Spring Convention 2026 to follow up on the successful implementation of the regulation

1) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282; 2) Van Haesendonck L., Ruof J., Desmet T., et al.: The role of stakeholder involvement in the evolving EU HTA process: Insights generated through the European Access Academy's multi-stakeholder pre-convention questionnaire. JMAHP 11, 1, (2023); 3) Julian E, Xander N, Boumaki K et al. Development of a Performance Measurement Framework for EU HTA. 2025; Submitted; JMAHP; 4) https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en

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The EAA Faculty is listed in the European Union Transparency Register and is a member of the HTA Stakeholder Network.

Selected Publications from the Topical Collection on EU HTA at the Journal of Market Access and Health Policy

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